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(54) Polymeric surgical staple

Chirurgische Klammer aus Polymerwerkstoff

Agrafe chirurgicale en matériaux polymères

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Description

[0001] This invention relates to surgical staples formed from an extruded "polymeric wire." The term "wire," as used in describing this invention, includes polymeric monofilaments. It has been found that wire (or monofilament fiber) extruded from polymer that is normally rigid at in vivo conditions can be used to form a surgical staple. The formation of a staple using the polymeric wire is accomplished using standard methods employed in the manufacture of metallic staples used in the surgical staple industry. Normally rigid polymers, when oriented by extrusion into polymeric wire according to this invention, have enhanced ductility in flexure. The terms "ductile" and "ductility" as used in describing this invention denote the property of permanent deformability, or plasticity, which may result from processes such as crazing or yielding. Specifically, ductile polymeric wires, when bent, will retain a large portion of the bend angle permanently (note that it is not required that the polymeric wires of this invention be ductile in tension along the fiber axis, only in bending or flexure) and the application of work is required to unbend the bent wire. This property can be used to form surgical staples simply by bending the polymeric wire as is done for metallic staples. This type of staple has great advantages over the types of staples in use today.

[0002] The current commercially available plastic staples are two-piece, injection molded devices. These staples are relatively large due to the need for the incorporation of an interlocking mechanism for joining the two staple pieces. The staples of the present invention have no requirement for an interlocking mechanism because the final form of the staple is accomplished simply by bending the polymeric wire, exactly as is done for metallic wires. The polymeric wire, not being as stiff as metal, requires a somewhat larger diameter to provide adequate holding power, but the final size is much more acceptable to the surgeon than the currently available plastic surgical staples.

[0003] The polymeric wire also has advantages over metallic wire. Metallic staples are known to be highly radiopaque, causing difficulties in reading X-ray images (both conventional and CT (computed tomography) scanning images) as well as MRI (magnetic resonance imaging) images due to what is known as the "starburst effect," a result of the high contrast of the metal to the tissue. These small areas of high contrast can cause difficulties in interpreting these images for subtle diagnostic purposes. Most polymers are known to be much more radio-transparent than metals. The reduced contrast between polymeric staples and tissue using these radio-imaging techniques eliminates the starburst effect. An additional advantage of polymeric staples over metal is that the polymeric staples can be formed from bioabsorbable polymers; thus, eliminating the risk of long term foreign body reactions of the tissue or staple migration that may be encountered with metal staples.

[0004] The patent and medical literature dealing with metallic staples and their uses in surgery is quite extensive. A review of surgical procedures involving internal staples and stapling devices can be found in the prior art. Because of the differences between metallic and polymeric staples, a detailed review of metallic staples is not necessary to illustrate the uniqueness of the present invention.

[0005] With regard to polymeric staples, the prior art describes the advantages of polymeric materials for staple applications. The majority of this prior art discloses a preference for absorbable polymers. Almost all of this prior art describes various polymeric materials for use in two-part, molded (not extruded) snap-together fasteners of various designs.

[0006] The prior art fasteners are not made from extruded, oriented polymeric wire and are not bent to form the final, implanted, staple shape. For example, the prior art describes a two-piece fastener where one of the components is formed from an extruded, "oriented crystalline polymeric material". The final, implanted, fastener form is achieved by mating the extruded portion with a molded portion, not by bending the oriented component.

[0007] Other prior art references describe one-piece staples made of absorbable or non-absorbable polymers. These references describe a mechanical locking-hinge mechanism to hold the staple legs in their final configuration. Tissue approximation of the devices described in these references is accomplished by bending at the hinge point until the locking mechanism engages. The devices described are not formed from extruded polymeric wire and are not formed or applied by bending an extruded polymeric wire. Another prior art reference describes a one-piece molded device that uses two barbed prongs to hold the tissue. This device is not formed from extruded polymeric wire and it is not formed or applied to tissue by bending.

[0008] Further prior art staples are known from GB-A-2 233 903, W0-A-88/05312 and EP-A-0 321 176.

[0009] The above-noted deficiencies of the prior art staples are overcome by the article of claims 1 to 7 and the process of claim 8.

Drawings

[0010]

Figures 1 and 2 are side views of a preformed and deformed staple of this invention;
Figure 3 is a top view of Figure 2;

Figure 4 is a top view showing the sequential in-vivo placement of the staple of Figure 3;
Figure 5 is a partial side view showing apparatus for deforming the staple of Figure 2;
Figures 6 and 7 are partial cutaway views on the respective planes 6-6 and 7-7 of Figure 5;
Figure 8 is a cutaway side view showing the creep testing of the staple deformed by Figure 5; and
Figure 9 is a graph showing the creep test results of Figure 8 versus time.

[0011] Surgical staples in use today appear in a number of forms, as required for the variety of types of procedures for which staples are used. A number of materials are used, but by a large margin the most commonly used material is stainless steel. One form currently used with metallic staples is what is known as a "B" shaped (for suturing parenchymal organs, the staples initially are a squared off "U"; they close to a "B", which is nonnecrosing, non-strangulating, and permits vessels and/or fluid flow to pass through the staple loops) staple typically used in internal procedures such as organ resections or bowel anastomoses. Prior to application of the staple to the tissue, the B staple "preform" resembles a squared-off version of the letter U -- very similar to the familiar paper staple. During the application of the B staple the "legs" of the staple are bent after passing through the tissue to form a shape resembling the letter B. The B shape is desirable as it provides a secure joining of tissue and stops blood flow from larger blood vessels, while allowing blood flow through smaller vessels (e.g. 1 mm in diameter or less) to continue; thus, preventing necrosis of the tissue to which the staple is attached. Another shape used with metals is the "box" staple, typically used for procedures such as fascia or skin closure. During application of this staple, the "backspan" of the staple preform (a shallow U shape) is bent at two points to form the final square or rectangular form. Other shapes are used as well, and all of the metallic forms (to our knowledge) require bending of the staple during application to the tissue to achieve the final staple shape.

[0012] It has been found that it is possible to produce staples for surgical use from polymeric wire. The requirements for a suitable polymer are that it be extrudable to form a monofilament of the required cross-sectional diameter, or length and width, and that it be permanently deformable (bendable) at room or body conditions. We have found that polymeric wire that is normally rigid at: body conditions of temperature and moisture perform well. The best results have been obtained with materials that have glass transition temperatures in excess of use temperature. Polymeric wire that is more flexible will not hold a permanent bend as well as rigid polymeric wire staples.

[0013] It has also been found that many bioabsorbable polymers can be successfully made into staples. Polymers such as polyglycolide and polylactide can be extruded to form monofilament polymeric wire, provided they have adequate melt viscosity properties. These polymeric wires can then be bent and formed into staples.

[0014] It has also been found that bioabsorbable copolymers can be successfully made into staples. Such copolymers may exhibit more than one solid phase, with at least one of the phases being continuous, i.e. the phase extends throughout the continuum of the staple without interruption or break. In this case it is desirable that the predominant continuous phase of the copolymer (if multiple phases are present) have a glass transition temperature above use temperature. The copolymer is a block copolymer. The continuous phase of such a copolymer is characterised by lactic acid ester linkages wherein said block copolymer can comprise linkages prepared from monomers selected from the group consisting of ε-caprolactone and 1,3-dioxane-2-one. Provided they have adequate melt viscosity properties, polymeric wire can be formed using conventional extrusion and fiber drawing techniques. These polymeric wires can then be bent and formed into staples.

[0015] It has also been found that blends of polymers can be used to form surgical staples. The blends can consist of absorbable or nonabsorbable polymers or copolymers or combinations thereof. For example, it is known that small amounts of finely divided microfibrous polytetrafluoroethylene will improve extrusion properties by increasing the melt viscosity of otherwise too fluid polymers. The second phase may also provide enhanced toughness to the polymeric wire.

[0016] The ductility of the polymeric wires may also make it possible to form other types of devices. One such device is a "twist tie" as is commonly used for holding objects together. The "twist" can be used in place of a knot. This could be of great use in noninvasive surgery techniques in use today where knot tying may be difficult.

[0017] The invention is further described in the following examples:

EXAMPLE 1: General polymerization procedure For l-Lactide Homopolymers:

[0018] l-Lactide, diethylene glycol (DEG), and stannous octoate were combined and melted under a nitrogen atmosphere. The mixture was charged into a nitrogen purged stirred reactor at 200°C. The contents were maintained at this temperature until maximum melt viscosity was achieved. The polymer was discharged from the reactor, ground and dried in a vacuum oven for 12-18 hours at 100°C and 27 Pa (0.2 mm Hg), Specific examples of polymers prepared by this procedure are summarized in Table 1.

EXAMPLE 2: General polymerization procedure for l-Lactide-b-TMC Copolymers:

[0019] Trimethylene carbonate (TMC), diethylene glycol (DEG), and stannous octoate were combined and melted under a nitrogen atmosphere. The mixture was charged into a nitrogen purged stirred reactor at 180°C. The contents were stirred at this temperature until maximum melt viscosity was achieved. 1-Lactide was melted under a nitrogen atmosphere and charged into the reactor. The reactor temperature was increased to 195°C over a 15 minute period. The contents were maintained at this temperature until maximum melt viscosity was obtained. The polymer was discharged from the reactor, ground and dried in a vacuum oven for 12-18 hours at 100°C and 27 Pa (0.2 mm Hg). Specific examples of polymers prepared by this procedure are summarized in Table 2.

EXAMPLE 3: General polymerization procedure for l-Lactide-b-Caprolactone Copolymers:

[0020] ε-caprolactone (CAP), diethylene glycol (DEG), and stannous octoate were combined and melted under a nitrogen atmosphere. The mixture was charged into a nitrogen purged stirred reactor at 200°C. The contents were stirred at this temperature until maximum melt viscosity was achieved. l-Lactide was melted under a nitrogen atmosphere and charged into the reactor. The contents were maintained at 200°C until maximum melt viscosity was obtained. The polymer was discharged from the reactor, ground and dried in a vacuum oven for 12-18 hours at 100°C and 27 Pa (0.2 mm Hg). Specific examples of polymers prepared by this procedure are summarized in Table 3.

EXAMPLE 4: General polymerization procedure for Glycolide Homopolymers:

[0021] Glycolide (Gly), lauryl alcohol (LA), and stannous chloride dihydrate were combined and melted under a nitrogen atmosphere. The mixture was charged into a nitrogen purged stirred reactor at 180°C. The temperature was increased to 225°C over a 45 minute period. The contents were maintained at 225°C until maximum melt viscosity was achieved. The polymer was discharged from the reactor, ground and dried in a vacuum oven for 12-18 hours at 100°C and 27 Pa (0.2 mm Hg). specific examples of polymers prepared by this procedure are summarized in Table 4.

EXAMPLE 5: Polymerization procedure for Glycolide-l-lactide Copolymers:

[0022] l-Lactide (1-Lac) (174.36g), Glycolide (Gly)(1.66g) and stannous octoate (50.0 mg) were combined and melted under a nitrogen atmosphere. The mixture was charged into a nitrogen purged stirred reactor at 180°C. The contents were stirred at this temperature for 80 minutes, at which point maximum melt viscosity was achieved. The temperature was then raised to 225°C over a 15 minute period. When this temperature was reached glycolide, which had been melted under a nitrogen atmosphere was charged into the reactor. The contents were then stirred at 225°C for 12 minutes. The polymer was discharged from the reactor, ground and dried in a vacuum oven for 12-18 hours at 100°C and 27 Pa (0.2 mm Hg). Specific examples of polymers prepared by this procedure are summarized in Table 5.

EXAMPLE 6: Extruded and Drawn Polymeric Wires Extrusion of l-Lactide rich polymeric wires:

[0023] Polymeric wires of different diameters to be used for test specimen preparation were extruded and drawn in the following manner. The polymer was dried in a vacuum oven prior to being added to the hopper of an extruder with a preheated barrel. It was extruded through a single jet with a diameter of 3 cm (0.120 inch). The extrudate was quenched in 25°C water at a distance of approximately 7,5 cm (3 inches) from the jet. The extrudate was then drawn in two stages while the strand was passing through two 120 cm (4 foot) long, circulating hot air ovens. The drawn polymeric wire was collected on a 9 cm (3.5 inch) diameter spool and stored in a dry environment. The specific extrusion conditions for the polymers of Examples 1, 2, 3 and 6 are shown in Table 6a. Some of the polymeric wires were redrawn in a secondary process as indicated in Table 6a. All of the l-lactide based polymeric wires listed in Table 6a and 6b were found to undergo ductile deformation when bent at room temperature.

Extrusion of polymeric wires composed of Glycolide homopolymer:

[0024] Polymeric wires of different diameters to be used for test specimen preparation were extruded and drawn in the following manner. The polymer was dried in a vacuum oven prior to being added to the hopper of an extruder with a preheated barrel. It was extruded through a single jet with a diameter of 2,2 mm (0.085 inch). The extrudate was quenched in 25°C water at a distance of approximately 19 mm (0.75 inches) from the jet. The extrudate was then drawn in two stages while the strand was passing through two 304,8 cm (10 foot) long, circulating hot air ovens. The drawn polymeric wire was collected on a 9cm (3.5 inch) diameter spool and stored in a dry environment. The specific extrusion conditions for the polymer of Example 4 are shown in Table 6a. All of the glycolide homopolymer based polymeric wires listed in Table 6a and 6b were found to undergo ductile deformation when bent at room temperature.

Extrusion of polymeric wires composed of polyethylene terephthalate (PET) (comparative experiment):

[0025] Polymeric wires of different diameters to be used for test specimen preparation were extruded and drawn in the following manner. The polymer was dried in a vacuum oven prior to being added to the hopper of an extruder with a preheated barrel. It was extruded through a single jet with a diameter of 3 cm (0.120 inch). The extrudate was quenched in 25°C water at a distance of approximately 7,5 cm (3 inches) from the jet. The extrudate was then drawn in two stages while the strand was passing through two 120 cm (4 foot) long, circulating hot air ovens. The drawn polymeric wire was collected on a 9 cm (3.5 inch) diameter spool and stored in a dry environment. The specific extrusion conditions for this polymer are shown in Table 6a. All of the PET based polymeric wires listed in Table 6a and 6b were found to undergo ductile deformation when bent at room temperature.

Extrusion of polymeric wires composed of polybutylene terephthalate (PBT) (comparative experiment):

[0026] A polymeric wire of approximately 0,45 mm (0.018 inch) diameter to be used for test specimen preparation was extruded and drawn in the following manner. The polymer was dried in a vacuum oven prior to being added to the hopper of an extruder with a preheated barrel. It was extruded through a single jet with a diameter of 2.2 mm (0.085 inch). The extrudate was quenched in 50°C water at a distance of approximately 2,5 cm (1 inch) from the jet. The extrudate was then drawn in two stages while the strand was passing through two 3 m (10 foot) long, circulating hot air ovens. The drawn polymeric wire was collected on a 9 cm (3.5 inch) diameter spool and stored in a dry environment. The specific extrusion conditions for this polymer are shown in Table 6a. The PBT based polymeric wire was found to undergo slight ductile deformation when bent at room temperature. Significant rebound, however, was observed.

Extrusion of polymeric wires composed of polybutester (a copolymer of polytetramethylene glycol and butylene terephthalate) (comparative experiment):

[0027] Commercial NOVAFIL® sutures (American Cyanamid Company, NJ 07470, U.S.A.) sizes 2, 1, and 0 were tested. The polybutester based polymeric wire was found to undergo slight ductile deformation when bent at room temperature. Significant rebound, however, was observed.

Polypropylene (PP) wire (comparative experiment):

[0028] Commercial PROLENE® sutures (Johnson & Johnson Co., NJ 08933, U.S.A.) sizes 2, 1, and 0 were tested. The PP based polymeric wire was found to undergo slight ductile deformation when bent at room temperature. Significant rebound, however, was observed.

Extrusion of polymeric wires composed of High Density Polyethylene (HDPE) (comparative experiment):

[0029] Polymeric wires of different diameters to be used for test specimen preparation were extruded and drawn in the following manner. The polymer was added to the hopper of an extruder with a preheated barrel. It was extruded through a single jet with a diameter of 1,5 mm (0.060 inch). The extrudate was quenched in 25°C water at a distance of approximately 7,5 cm (3 inches) from the jet. The extrudate was then drawn in two stages while the strand was passing through two 1,2 m (4 foot) long, circulating hot air ovens. The drawn polymeric wire was collected on a 9 cm (3.5 inch) diameter spool. The specific extrusion conditions are shown in Table 6a. The HDPE based polymeric wire was found to undergo some ductile deformation when bent at room temperature. Slow rebounding of the bend was observed to occur.

Dimensional and Mechanical Testing of Polymeric wires:

[0030] The diameter, tensile strength, and modulus of the drawn polymeric wires listed in Table 8a were determined in the following manner. The polymeric wire diameter was determined under a specified pressure applied by the presser foot of a gauge. The gauge was of the dead-weight type and equipped with a direct reading dial graduated to 0.002 mm. The tensile strength and modulus were determined using an Instron testing machine (Instrom Engineering Corp., MA U.S.A.). The mean dimensional measurements and tensile values are reported in Table 6b.

EXAMPLE 7: Molded plaque of l-Lactide-trimethylene carbonate copolymer:

[0031] Polymer from example 2.g was molded into a plaque for test specimen preparation using a heated hydraulic press. At a press temperature of 200°C, about 23 grams of dry polymer granules were pressed in a 10.1 cm × 10.1 cm × 1.6 cm (4.25 inch by 4.25 inch by 0.062 inch) steel frame between a polytetrafluoroethylene coated release liner fabric at 225 kg (500 pounds) of pressure for 4 minutes followed by a pressure increase to 2250 kg (5000 pounds) for 4 minutes. The hot plaques were cooled between chilled aluminum plates. The plaques were removed from the frame and annealed in the press at about 112 kg (250 pounds) 96.10^3Pa (14 psi) pressure.

[0032] The material was found to break when bent at room temperature. The flexural properties were measured using ASTM method D790 (American Society For Testing And Materials, PA 19103, U.S.A.). The modulus was 4900 MPa (710,000 psi), the strength at break was 96MPa (14,000 psi), and the strain at break was 21.6%. No yield point was observed. This example illustrates that without the enhancement in bending ductility provided by forming an oriented wire, the 95/5 l-Lac/TMC material does not yield in flexure. For comparison see example 6, sample 9 which was found to perform well as a staple material.

EXAMPLE 8: Thermal Analysis of Copolymers and Polymers

[0033] Samples of the polymers of Examples 1 to 5 and 6 were analyzed by differential scanning calorimetry (DSC) using a Perkin Elmer DSC-4 instrument (Perkin Elmer Company, CT U.S.A.).Scanning conditions were from -40°C to 240°C at 20°C minimum under nitrogen. Melting points (Tm) and enthalpy of fusion (H_f) values were determined by scanning material that had been annealed at 110°C for 16 hours. The glass transition temperatures (Tg) were determined after quenching the specimen from the melt following the first scan. Some of the samples exhibited two Tg's in the temperature region scanned: Tg(1) and Tg(2). The presence of two Tg's indicates the sample has two amorphous phases. The results of the thermal analyses are shown in Table 7. Several fiber samples were analyzed in the same way as the polymer samples. These fiber results are also shown in Table 7.

EXAMPLE 9 : Preformed Staple Formation:

[0034] Staples were shaped and pointed in a manner which is similar to conventional metal staple forming. Only selected lengths of the polymeric wires of Example 6 were used for making preformed staples. The diameter of the chosen polymeric wire lengths was limited to three sizes: 0.05, 0.045, 0.038 cm (0.021, 0.018, and 0.015 inch) (each size ± 0.0025 mm (±0.001 inch)). The polymeric wire was formed into a U-shape by bending it at room temperature over two radii of approximately 0.25 mm (0.010 inch) to a 90° angle.

[0035] The minimal force to bend the polymeric wire completely around the anvil without damaging it was applied. While the polymeric wire was held against the anvil, each staple point was formed by shearing the polymeric wire at a 45° angle to the long axis of the polymeric wire with a steel cutting blade. The length of each leg of the staple was approximately 0.47 cm (0.185 inch). The preformed staple was then released from the anvil. The staples were washed in a 1% solution of a nonionic surfactant in water. They were then thoroughly rinsed in deionized water and methanol. The staples were dried at room temperature under vacuum to remove all water and methanol residues. The final preformed staple is shown in Figure 1.

[0036] In its preformed state shown in Figure 1, the surgical staple or staple blank 10 in accordance with the present invention is generally U-shaped as are conventional staples. The legs 14 are shown in parallel form, which is the conventional configuration for staples placed in a surgical stapler track. However, the surgical staple of this invention after being preformed (and before being placed in the stapler track) may relax such that the legs 14 are oblique to each other. Thus the staple 10 includes a back span 12, two legs 14, and an end point 16 formed at the extreme of each leg 14. The end points are sharply chiseled to cleanly pierce the body organs or tissue to be sutured. However, while the polymeric staple is deformable, the end points may be brittle and can break or crush if pressed against a bard surface.

[0037] Figures 2 and 3 show the staple 10 of Figure 1 in its deformed state. As shown, the legs 14 are bent from their configuration perpendicular (they can also be oblique) to the back span 12 into an arcuate shape with the end points 16 extending toward opposite sides of the back span 12. Thus the brittle end points 16 do not encounter the underside of the back span 12 during deformation, and breaking or crushing of them is mitigated. Preferably, one end point 16 is guided toward one side of the back span and the other end point is guided toward the other side of the back span to further prevent the end points from engaging each other. The end points may desirably be closely adjacent opposite sides of the back span and may extend beyond or past the back span. The end points can also be bent so that each extends in an opposite direction across an axial plan A-A perpendicular to the back span 12 of the staple.

[0038] As shown in Figure 4, the end points 16 should be guided sufficiently close to the back span 12 so the staple in-vivo body organ 50 cannot work its way off of the end points.

EXAMPLE 10: Measurement of Permanent Bend Angle

[0039] A measurement of the permanent deformation after bending the 0.6 mm (0.022 inch) diameter l-lactide/trimethylene carbonate polymeric wire under staple preform formation conditions was made. This served as a measure of the ductility in bending of the polymeric wire, and can be considered as a test for suitability of a polymeric wire material for use as a staple. The wire was bent over a radius of approximately 0.25 mm (0.010 inch) to a 90° angle by using the staple forming fixture of example 9. The specimen was removed from the fixture and immediately placed on an optical comparator at a magnification of 50X. The angle between the shaped leg and the backspan was measured. The measurement was repeated 0.5, 1, 4, and 24 hours after the staple was formed. The results are summarized in table 8.

EXAMPLE 11: Sterilization of Preformed Staples:

11.a: EtO sterilization of l-Lac/TMC polymeric wires:

[0040] The polymeric staples were packaged in paper support cards which were then inserted into foil laminate envelopes. During this step of the packaging process, the staples were stored overnight in a dry environment. The open foil envelopes and their contents were sterilized by exposure to ethylene oxide (ETO) and then vacuum dried. After vacuum drying, the staples and open foil envelopes were always stored or handled in a dry environment until the foil envelopes were aseptically heat sealed. After outer Tyvek® / Mylar® film (DuPont Co., DE, U.S.A.) pouches were applied, the outside surfaces of the foil envelopes were sterilized by exposure to ethylene oxide. Staples formed from polymeric wire from example 6, sample 4 were sterilized by ETO for testing.

11.b - d Radiation Sterilization of l-Lac/TMC polymeric wires:

[0041] In a dry environment, the polymeric staples formed from the polymeric wire from example 6, sample 4, were packaged in predried paper support cards which were then inserted into foil laminate envelopes. The foil envelopes were heat sealed and packaged in Tyvek® /Mylar® film outer pouches. The finished packages were sterilized via Cobalt 60 radiation at doses of 2.5 Mrad minimum to 3.0 Mrad maximum (example 11.b) or 5.0 Mrad minimum to 7.0 Mrad maximum (examples 11.c and 11.d).

11.e - g Radiation Sterilization of l-Lac/Cap polymeric wires:

[0042] In a dry environment, the polymeric staples formed from the polymeric wire from example 6, samples 10, 11 and 12, were packaged in predried paper support cards which were then inserted into foil laminate envelopes. The foil envelopes were heat sealed and packaged in Tyvek® /Mylar® film outer pouches. The finished packages were sterilized via Cobalt 60 radiation at doses of 2.5 Mrad minimum to 3.0 Mrad maximum. The sterile staples from example 6, samples 10, 11 and 12 were designated examples 11.e, 11.f and 11.g respectively.

EXAMPLE 12: Formation and testing of Formed Staples

Staple formation:

[0043] The preformed staples of Example 9 could be implanted into various materials by using a delivery system which operated similarly to a metal stapler. Referring to Figure 5, the delivery system consisted of two mating halves -- a cartridge 30 and an anvil 31. Each preformed staple (shown in Figure 1) was loaded into a slot 32 in the cartridge such that the staple legs would be pushed against the anvil when the tool was activated. The anvil consisted of a number of specially designed pockets 33 which bent the staple legs as the staple was moved forward through the cartridge. A description of anvil pockets which can be used in this application is described in EP application Serial Number 92 116 976.9 filed October 5, 1992. The anvil pockets were designed so that the staple points, after passing through the pocket, would pass by the staple backspan on opposite sides. A single formed staple is shown in Figure 2 and 3 herein.

[0044] The delivery device had a sufficient number of slots 32 and anvil pockets 33 to form two rows of staples approximately 2.54 cm (1 inch) in length as shown in Figure 4. Staple rows of this type are commonly used to suture parenchymal organs.

[0045] The gap between the bottom surface 34 of the cartridge and the anvil was 1 cm (0.040 in). The slot length (more fully shown in figure 6) was 4 mm (0.166 in). Referring to figure 6, the slot extensions 32a accommodate the staple ends 16 (shown in figures 2 and 3) if they pass over the top of the back span 12. The height h_1 is about 0.125

mm (0.005 inches) greater than the diameter of the chosen polymeric wire (see, e.g., example 9 above). The height h_2 is approximately equal to three times h_1. Referring again to figure 5, the pusher 36 (more fully shown in figure 7) fits snugly into the slot and has a squared-off, flat end to provide uniform pressure across the back span 12 (shown in figure 1) during the forming stroke. Referring to figure 7, the height h_3 is approximately equal to the diameter of the chosen polymeric wire described in example 9 above. The length of the slot 32 and the pusher 36 (with the pusher length being about 0.125 mm (0.005 inches) less than the slot length) is approximately equal to the length of the back span 12, shown e.g. in figure 3.

[0046] At the completion of the staple formation stroke, the pusher 36 extended 0.25 mm (0.010 in) beyond the slot opening 32 into the gap. A slide bar 40 was used to move the pusher 36 during the staple formation stroke.

Staple opening strength testing:

[0047] The opening strength of the staple was determined in the following manner. A single staple was loaded into the delivery system and formed through two layers of polyethylene (each 0.1 cm (0.004 inches) thick X 2.5 cm (1.0 inches) wide X 12.5 cm (5 inches) long). The staple was centered in the polyethylene strips and the backspan of the staple was perpendicular to the long axis of the strips. The same anvil pocket was used to form each staple. These specimens were tested before conditioning or after a specified in vitro conditioning period (7, 14, 21, 28, 35, or 42 days in 6.09 pH, 37 ± 0.2°C buffer solution). The mechanical testing was performed using an Instron testing machine (Instron Engineering Corp., MA U.S.A. The strength of each staple was determined by folding each polyethylene sheet back on itself and gripping the ends such that the two legs of the staple would open evenly when the Instron crosshead was activated. The maximum load recorded during the test was defined as the opening strength of the staple. The results of the mechanical testing are summarized in Table 9.

EXAMPLE 13: Preclinical Testing:

[0048] Using aseptic technique, an end-to-end, everting anastomosis of the small bowel of a beagle was performed using a prototype delivery device (See example 12) and ethylene oxide sterilized staples of 0.56 mm (0.022 inch) diameter 80/20 l-lactide/trimethylene carbonate wire (example 11.b). A second end-to-end, everting anastomosis was performed approximately 35.5 cm (approximately 14 inches) away in the bowel using a commercially available internal stapler which delivered a double row of 0.23 mm (0.009 inch) diameter stainless steel staples (Auto Suture® TA-55 surgical stapler, United States Surgical Corp., Ct. U.S.A.). Prior to closing the wound, saline was injected into the bowel proximal to each anastomosis, demonstrating patency and water tightness. The laparotomy was closed using standard technique. The dog was euthanized 8 days postoperatively in order to evaluate the two anastomoses.

[0049] Gross examination of the anastomoses, both the polymeric and metal staple procedures, revealed that they were patent and nonstenotic. Healing appeared to be progressing normally. For each anastomosis, a segment of the bowel containing the operative site was removed and burst hydraulically. The 8 day polymeric staple anastomosis burst at 56 kPa (420 mm Hg), and the 8 day metal staple anastomosis burst at 53 kPa (400 mm Hg). All specimens were then opened longitudinally, trimmed and examined. The mucosal surfaces appeared similar at the polymeric and metal staple anastomoses.

EXAMPLE 14: Creep Testing of Formed Staples:

[0050] As shown in Figure 8, a staple 10 formed from 0.56 mm (0.022 inch) diameter lactide/TMC polymeric wire (Table 6a, sample 4) were subjected to two different weights while immersed in 37°C normal saline. The displacement d_1 of the staple legs was measured for up to 17 days.

[0051] Each staple was formed through two 0.05 mm (0.002 inch) thick Mylar® films (DuPont Co., DE U.S.A.) 70. Each film of Mylar® was folded back upon itself, and a weight (72g or 50g in air) was attached to the lower half of the test. The specimens were then hung in a tank of 37°C normal saline. The distance from top of the staple backspan 12 to the bottom of the staple leg 14 was measured using a camera and a video micro scaler system. Measurements were taken at 2 minutes (baseline), 1 hour, and 1, 3, 6, 8, 11, 13, 14, and 17 days. After 17 days, the specimens were carefully removed from the tank, and the breaking strength of the staples was determined on an Instron testing machine.

[0052] The results of the creep test are summarized in Table 10. The mean displacement with time is also shown graphically in Figure 9. The mean displacement of the specimens with the 72g weight increased to 0.35 mm (0.014 inch) (18% of baseline staple height) at 6 days and then remained constant up to 17 days. For the specimens with the 50g weight, the mean displacement increased to 0.27 mm (0.011 inch) (14%) at 6 days, and then remained constant up to 17 days.

[0053] After creep testing, the opening strengths of the test specimens were determined as described in example 12. The overall mean opening strength of the staples was 686 grams (674 g for the 72 gram test and 698 g for the 50 gram test).

Table 1: Poly(l-Lactide Homopolymers)

	Charged Composition					Polymerization	Analyzed Composition	
	l-Lactide	DEG[1]		Stannous octoate		Time	l-Lactide	IV
Example	(grams)	(mg)	(mole %)[2]	(mg)	(mole %)[2]	(Hr:Min)	(mole %)[3]	(CHCl3)[4]
1.a	230.0	8.5	0.005	19.4	0.003	2:26	100	1.76
1.b	230.0	8.5	0.005	19.4	0.003	1:28	100	1.90
1.c	230.0	8.5	0.005	19.4	0.003	1:52	100	1.79
1.d	250.0	239	0.130	21.1	0.003	3:25	100	1.34

1) DEG = diethylene glycol.

2) Based on moles of l-lactide.

3) Determined by ^1H-Nuclear Magnetic Resonance spectroscopy. In all cases the level of residual monomer was found to be <0.5 wt%.

4) Inherent Viscosity, measured in Chloroform at 30°C, polymer concentration = 0.5g/dL.

TABLE 2: Poly(l-Lactide-b-TMC)

	Charged Composition						Polymerization		Analyzed Composition	
					Stannous		Time (Hr:Min)			
	l-Lac/TMC		DEG[1]		octoate		Reaction Stage		l-Lac/TMC	IV
Example	(grams)	(mole%)	(mg)	(mole%)[2]	(mg)	(mole%)[2]	1	2	(mole%)[3]	(CHCl$_3$)[4]
2.a	199.95/35.40	80/20	239	0.13	21.1	0.003	1:25	1:09	77.1/22.9	1.21
2.b	225.00/17.66	90/10	239	0.13	21.1	0.003	1:34	0:57	90.1/9.9	1.31
2.c	5944/1056	80/20	490	0.01	505	0.003	0:45	3:30	79.2/20.8	1.50
2.d	212.46/26.54	85/15	18.4	0.01	21.1	0.003	1:24	1:56	85.3/14.7	1.91
2.e	225.00/17.66	90/10	18.4	0.01	21.1	0.003	0:24	2:25	90.1/9.9	1.93
2.f	237.50/8.88	95/5	18.4	0.01	21.1	0.003	0:25	2:54	94.7/5.3	1.71
2.g	205.34/7.66	95/5	16.9	0.01	18.2	0.003	0:21	3:40	95.3/4.7	1.65

1) DEG = Diethylene glycol

2) Based on moles of l-Lactide plus TMC.

3) Determined by ^{1}H-Nuclear Magnetic Resonance spectroscopy. In all cases residual monomer was <0.5 wt%.

4) Inherent viscosity, measured in Chloroform at 30°C, polymer concentration = 0.5g/dL.

TABLE 3: Poly(Caprolactone-b-l-Lactide)

	Charged Composition						Polymerization		Analyzed Composition	
					Stannous		Time (Hr:Min)			
	l-Lac/Cap		DEG[1]		octoate		Reaction Stage		l-Lac/Cap	IV
Example	(grams)	(mole%)	(mg)	(mole%)[2]	(mg)	(mole %)[2]	1	2	(mole%)[3]	(CHCl$_3$)[4]
3.a	201.35/35.00	80/20	18.1	0.01	20.7	0.003	1:03	2:07	81.9/18.2	1.80
3.b	170.38/29.62	80/20	15.3	0.01	17.3	0.003	1:03	1:59	81.4/18.6	1.76
3.c	170.38/29.62	80/20	15.3	0.01	17.3	0.003	0:48	2:45	80.6/19.4	1.69
3.d	170.38/29.62	80/20	15.3	0.01	17.3	0.003	0:48	2:50	81.1/18.9	1.84
3.e	213.75/11.25	95/5	16.6	0.01	19.0	0.003	0:38	2:54	94.1/5.9	1.74
3.f	213.75/11.25	95/5	16.6	0.01	19.0	0.003	0:28	3:00	93.6/6.4	1.74

1) DEG = Diethylene glycol.

2) Based on moles of l-Lactide plus Cap.

3) Determined by ^{1}H-Nuclear Magnetic Resonance spectroscopy. In all cases residual monomer was <0.5 wt%.

4) Inherent viscosity, measured in Chloroform at 30°C, polymer concentration = 0.5g/dL.

TABLE 4: Poly(glycolide)Homopolymers

	Charged Composition					Polymerization	Analyzed Composition	
	Glycolide	LA[1]		$SnCl_2 \cdot 2H_2O$		Time	Glycolide	IV
Example	(grams)	mg	(mole%)[2]	mg	(mole%)[2]	(Hr:Min)	(mole%)[3]	(HFAS)[4]
4.a	250.00	20.1	0.005	2.4	0.0005	2:19	100	1.06
4.b	250.00	20.1	0.005	2.4	0.0005	4:30	100	0.95

1) LA = lauryl alcohol

2) Based on moles of glycolide.

3) Measured by ^{1}H-Nuclear Magnetic Resonance spectroscopy. In all cases residual monomer <0.5 wt%.

4) Inherent viscosity, measured in hexafluoroacetonesesquihydrate at 30°C, polymer concentration = 0.5g/dL.

TABLE 5: Poly(Glycolide-l-Lactide)Polymers

	Charged Composition				Polymerization Time (Hr:Min) Reaction Stage		Analyzed Composition	
	l-Lactide/Gly		$SnCl_2 \cdot 2H_2O$				l-Lac/Gly	IV
Example	(grams)	(mole%)	(mg)	(mole%)[1]	1	2	(mole%)[2]	(HFAS)[3]
6.a	174.36/61.69	71/29	50.0	0.013	1:31	0:12	67.3/32.7	1.30
6.b	174.36/61.69	71/29	50.0	0.013	1:32	0:14	64.1/35.9	1.12

1) Based on moles Glycolide plus l-Lactide.

2) Measured by ^{1}H-Nuclear Magnetic Resonance spectroscopy. In all cases residual monomer <0.5 wt%.

3) Inherent viscosity, measured in hexafluoroacetonesesquihydrate at 30°C, polymer concentration = 0.5 g/dL.

TABLE 6a:

Polymeric Wire Extrusion Conditions

Polym. wire sample	Polymer From Example	Polymer	Final Diamete (mm)	Head Temp. (°C)	1st Draw Ratio	1st Oven Temp (°C)	2nd Draw Ratio	2nd Oven Temp (°C)	Redraw Draw Ratio	Oven Temp (°C)
1	1.a-c	poly(l-lactide)	0.522	220	4.91	107	1.09	115		
2	1.a-c	poly(l-lactide)	0.454	220	5.48	107	1.10	107		
3	1.a-c	poly(l-lactide)	0.383	220	6.04	108	1.11	116		
4	2.c	80/20 lactide/TMC	0.548	225	5.22	95	1.11	115	1.23	114
5	2.c	80/20 lactide/TMC	0.444	225	5.20	95	1.10	133	1.66	125
6	2.c	80/20 lactide/TMC	0.415	225	6.15	99	1.08	134	1.23	115
7	2.d	85/15 lactide/TMC	0.538	215	5.33	98	1.08	117	1.25	111
8	2.e	90/10 lactide/TMC	0.544	221	5.30	96	1.13	116	1.22	110
9	2.f	95/5 lactide/TMC	0.541	230	5.34	94	1.13	115	1.22	111
10	3.c-d	80/20 lactide/cap	0.557	215	5.68	89	1.09	100		
11	3.c-d	80/20 lactide/cap	0.467	216	5.94	89	1.10	99		
12	3.c-d	80/20 lactide/cap	0.394	216	5.73	90	1.10	99		
13	3.e-f	95/5 lactide/cap	0.529	217	5.29	98	1.13	111		
14	3.e-f	95/5 lactide/cap	0.484	215	5.64	100	1.11	113		
15	3.e-f	95/5 lactide/cap	0.374	215	5.76	100	1.11	113		

TABLE 6a: (continued)

Polymeric wire Extrusion Conditions

Polym. wire Sample	Polymer From Example	Polymer	Final Diameter (mm)	Head Temp. (°C)	1st Draw Ratio	1st Oven Temp (°C)	2nd Draw Ratio	2nd Oven Temp (°C)	Redraw Draw Ratio	Oven Temp (°C)
16	4.a-b	Polyglycolide	0.539	249	5.43	65	1.00	149		
17	4.a-b	Polyglycolide	0.457	248	5.45	65	1.00	149		
18	4.a-b	Polyglycolide	0.385	249	6.23	60	1.10	111		
19	4.a-b	Polyglycolide	0.381	248	5.44	65	1.00	149		
21	5.a-b	25/75 glycolide/l-lac	0.641	215	4.21	92	1.14	113		
22	5.a-b	25/75 glycolide/l-lac	0.582	215	5.11	87	1.11	113		
23	5.a-b	25/75 glycolide/l-lac	0.385	215	5.55	89	1.09	113		
24		PET	0.442	277	5.30	77	1.01	138		
25		PET	0.374	278	5.42	73	1.02	142		
26		PET	0.368	279	5.45	82	1.02	141		
27		PBT	0.477	250	4.00	180	1.25	180		
28		HDPE	0.525	201	8.68	122	1.11	124		
29		HDPE	0.491	201	8.85	87	1.11	101		
30		HDPE	0.478	200	10.11	110	1.11	110		

TABLE 6a: (continued)

Polymeric wire Extrusion Conditions

Polym. wire Sample	Polymer From Example	Polymer	Final Diameter (mm)	Head Temp. (°C)	1st Draw Ratio	1st Oven Temp (°C)	2nd Draw Ratio	2nd Oven Temp (°C)	Redraw Draw Ratio	Redraw Oven Temp (°C)
31		HDPE	0.439	200	9.43	123	1.11	127		
32		HDPE	0.381	201	10.00	124	1.11	127		
33		Polybutester	0.598	Commercially available suture						
34		Polybutester	0.492	Commercially available suture						
35		Polybutester	0.381	Commercially available suture						
36		PP	0.487	Commercially available suture						
37		PP	0.468	Commercially available suture						
38		PP	0.381	Commercially available suture						

TABLE 6b

POLYMERIC WIRE MECHANICAL PROPERTIES

Polym. Wire Sample	Polymer From Example	Polymer	Diameter (mm)	Modulus (10^3 psi)	At Break Strength (10^3 psi)
1	1.a-c	poly(l-lactide)	0.522	1047	54.0
2	1.a-c	poly(l-lactide)	0.454	1102	63.0
3	1.a-c	poly(l-lactide)	0.383	1066	59.9
4	2.c	80/20 lactide/TMC	0.548	991	51.2
5	2.c	80/20 lactide/TMC	0.444	1061	59.7
6	2.c	80/20 lactide/TMC	0.415	1074	53.9
7	2.d	85/15 lactide/TMC	0.538	1048	58.9
8	2.e	90/10 lactide/TMC	0.544	1088	60.4
9	2.f	95/5 lactide/TMC	0.541	1197	61.2
10	3.c-d	80/20 lactide/cap	0.557	821	47.8
11	3.c-d	80/20 lactide/cap	0.467	846	53.5
12	3.c-d	80/20 lactide/cap	0.394	933	54.9
13	3.e-f	95/5 lactide/cap	0.529	1036	59.8
14	3.e-f	95/5 lactide/cap	0.484	1029	59.4
15	3.e-f	95/5 lactide/cap	0.374	1064	60.7
16	4.a-b	Polyglycolide	0.539	1519	47.0
17	4.a-b	Polyglycolide	0.457	1771	60.7
18	4.a-b	Polyglycolide	0.385	1896	73.7
19	4.a-b	Polyglycolide	0.381	2053	92.2
21	5.a-b	25/75 gly/lac	0.641	766	35.9
22	5.a-b	25/75 gly/lac	0.582	797	45.5
23	5.a-b	25/75 gly/lac	0.385	894	50.0
24		PET	0.442	1839	91.1
25		PET	0.374	2010	98.5

1 psi = 6.9×10^3 Pa

TABLE 6b (continued)

POLYMERIC WIRE MECHANICAL PROPERTIES

Polym. Wire Sample	Polymer From Example	Polymer	Diameter (mm)	Modulus (10^3 psi)	At Break Strength (10^3 psi)	At Break Strain (%)
26		PET	0.368	1920	103.6	9.5
27		PBT	0.477	507	55.9	27.1
28		HDPE	0.525	999	52.2	6.0
29		HDPE	0.491	1140	54.4	6.4
30		HDPE	0.478	1160	52.3	4.5
31		HDPE	0.439	1203	53.3	5.8
32		HDPE	0.381	1302	56.0	4.8
33		Polybutester	0.598	220	69.8	33.0
34		Polybutester	0.492	305	76.7	30.9
35		Polybutester	0.381	Not tested		
36		PP	0.487	453	67.2	30.7
37		PP	0.468	428	61.7	37.6
38		PP	0.381	Not tested		

1 psi = 6.9×10^3 Pa

TABLE 7

Thermal Analysis Data

Polym. Wire Sample	Polymer From Example	Polymer	Tg(1) (°C)	Tg(2) (°C)	Tm (°C)	ΔH_f (J/g)	% Cryst.[1]
(see Table 6a)	1a	poly(l-lactide)	63.2	‡	177.0	52.85	56.9
	2a	80/20 lactide/TMC	3.4	59.8	175.3	39.39	43.0
	2d	95/15 lactide/TMC	-9.9	60.8	174.2	46.89	50.5
	2e	90/10 lactide/TMC	9.2	61.2	176.3	52.52	56.6
	2f	95/5 lactide/TMC	-10.4	60.8	175.7	51.87	55.9
	3a	80/20 lactide/cap	†	ca. 60*	50.4, 173.8§	5.81, 44.65§	4.3, 48.1§
	3c	95/5 lactide/cap	†	63.6	49.6, 178.1§	1.34, 55.25§	1.0, 59.5§
	4a	poly(glycolide)		43.6‡	224.9	82.74	43.7

* Tg obscured by endotherm, ** Unable to determine Tg, † Tg below scan range, ‡ single amorphous phase, § two crystalline phases

1. Calculated using ΔH_f values of 100% crystalline polymer taken from "Polymer Handbook", Third Edition, J Brandrup and E. H. Immergut, John Wiley and Sons, 1989.

TABLE 7

(Continued)

Thermal Analysis Data

Polym. Wire Sample	Polymer From Example	Polymer	Tg(1) (°C)	Tg(2) (°C)	Tm (°C)	ΔH_f (J/g)	% Cryst.[1]
	5a	25/75 glycolide/l-lac	45.7	62.0	167.1	33.14	35.7
24		PET	82.8	‡	249.9	51.35	36.7
27		PBT	41.7	‡	224.8	55.06	39.1
28		HDPE	†	‡	137.8	215.85	74.6
33		Polybutester	**	**	216.1	57.60	40.9
36		PP	-3	‡	154.5	106.2	64.5

* Tg obscured by endotherm, ** Unable to determine Tg, † Tg below scan range, ‡ single amorphous phase, § two crystalline phases

1. Calculated using ΔH_f values of 100% crystalline polymer taken from "Polymer Handbook", Third Edition, J Brandrup and E. H. Immergut, John Wiley and Sons, 1989.

TABLE 8

Bend Angle Measurement of 0.56 mm 0.022 inch Diameter Preformed Staples

Retained Bend Angle (degrees)

Table 6a

		Time After Bending														
		0 Hours			0.5 Hours			1 Hours			4 Hours			24 Hours		
Sample	Polymer	n	Mean	S.D.	n	Mean	S.D.	n	Mean	S.D.	n	Mean	S.D.	n	Mean	S.D.
4	80/20 lac/TMC	5	117	4.8	5	120	4.6	5	121	4.2	5	122	3.9	5	123	3.3
7	85/15 lac/TMC	5	114	1.9	5	118	2.5	5	120	3.2	5	121	3.4	4	123	2.3
8	90/10 lac/TMC	5	115	2.2	5	120	2.0	5	121	1.9	5	122	2.0	5	123	2.3
9	95/5 lac/TMC	5	116	2.6	5	120	1.9	5	121	2.1	5	122	1.9	5	123	1.6

TABLE 9

Opening Strength (g)

			In Vitro Time (days)																				
Table 6a			0 Days			7 Days			14 Days			21 Days			28 Days			35 Days			42 Days		
Sample	Polymer	Diam. (in)	n	Mean	S.D.	n	Mean	S.D.	n	Mean	S.D.	n	Mean	S.D.	n	Mean	S.D.	n	Mean	S.D.	n	Mean	S.D.
1	PLLA	0.021	5	592	31.3	5	729	34.9	5	815	51.8	5	839	35.6	5	793	36.0	5	882	36.3	4	798	72.9
2	PLLA	0.018	5	318	69.8	5	454	80.7	5	484	91.3	5	598	65.4	5	470	94.1	5	520	47.7	5	528	65.9
3	PLLA	0.015	5	177	38.5	4	214	42.9	5	212	46.4	5	248	58.0	5	242	68.9	5	246	57.6	5	308	67.0
4	80/20 lac/TMC	0.022	5	497	49.4	4	603	65.0	5	693	78.7	5	629	63.9	5	584	62.8	5	735	58.5	5	771	113.6
5	80/20 lac/TMC	0.018	5	262	19.6	5	281	76.0	5	314	81.1	5	280	19.0	5	360	77.1	5	338	35.1	5	329	98.2
6	80/20 lac/TMC	0.016	5	190	22.2	5	241	43.5	5	245	33.0	5	199	30.9	5	294	40.8	5	242	47.0	5	294	17.1
7	85/15 lac/TMC	0.021	5	520	60.7	5	655	89.9	5	710	114.2	5	725	25.7	5	525	36.3	5	640	79.0	5	657	82.6
8	90/10 lac/TMC	0.021	5	541	72.0	5	603	64.8	5	757	107.1	5	762	76.9	5	693	103.8	5	832	132.1	5	815	44.0
9	95/5 lac/TMC	0.021	5	657	48.6	5	831	54.7	5	823	133.3	5	804	88.5	5	807	149.2	5	840	92.5	5	791	154.8
10	80/20 lac/cap	0.021	5	459	54.8	5	706	90.4	5	655	72.2	5	755	40.4	5	760	102.3	5	751	72.8	5	713	74.2
11	80/20 lac/cap	0.018	5	340	62.0	5	431	88.5	5	496	106.7	5	458	108.7	5	557	189.7	5	564	90.2	5	574	126.6
12	80/20 lac/cap	0.015	5	205	118.2	5	245	40.8	5	410	163.3	5	400	84.0	5	214	20.3	5	346	186.3	5	221	99.2
13	95/5 lac/cap	0.021	5	550	132.2	5	686	111.5	5	684	108.2	5	674	64.7	5	782	85.7	5	780	110.5	5	755	135.5

1 in = 25.4 mm

TABLE 9 (continued)

Opening Strength (g) of Sterilized Staples

			In Vitro Time (days)																				
			0 Days			7 Days			14 Days			21 Days			28 Days			35 Days			42 Days		
Example	Polymer	Diam. (in)	n	Mean	S.D.	n	Mean	S.D.	n	Mean	S.D.	n	Mean	S.D.	n	Mean	S.D.	n	Mean	S.D.	n	Mean	S . D .
13.a	80/20 lac/TMC (EtO)	0.022	6	442	36.0	6	584	85.3	6	593	85.8				6	621	57.4						
13.b	80/20 lac/TMC (2.5 Mrad)	0.022	6	510	89.0	6	667	43.5	6	692	72.2				6	734	162.1						
13.c	80/20 lac/TMC (5 Mrad)	0.022	6	456	73.3	6	710	110.8	6	689	69.3	6	688	101.8	5	660	173.6						
13.d	80/20 lac/TMC (5 Mrad)	0.022	6	560	67.4	6	543	76.7	6	560	117.7	6	641	96.3	6	587	79.2						
13.e	80/20 lac/cap (2.5 Mrad)	0.021	5	524	44.6	5	600	48.6	5	627	56.5	5	601	49.9	5	523	101.3	5	543	65.6	5	514	55.3
13.f	80/20 lac/cap (2.5 Mrad)	0.018	5	283	48.2	4	361	91.2	5	356	66.2	5	319	66.6	5	345	92.9	5	395	130.0	4	340	70.6
13.g	80/20 lac/cap (2.5 Mrad)	0.015	5	153	13.4	5	162	38.2	5	192	27.1	5	226	50.9	5	202	16.2	5	170	28.7	5	197	31.9

* 8 days

1 in = 25,4 mm

TABLE 9 (continued)

Opening Strength (g)

Table 6a

			In Vitro Time (days)																				
			0 Days			7 Days			14 Days			21 Days			28 Days			35 Days			42 Days		
Sample	Polymer	Diam. (in)	n	Mean	S.D.	n	Mean	S.D.	n	Mean	S.D.	n	Mean	S.D.	n	Mean	S.D.	n	Mean	S.D.	n	Mean	S.D.
14	95/5 lac/cap	0.018	5	465	103.4	5	660	121.4	5	697	213.3	5	716	186.8	5	703	96.6	5	718	308.2	5	850	212.9
15	95/5 lac/cap	0.015	5	186	50.5	5	377	173.4	5	304	73.1	5	347	84.5	5	319	91.3	5	317	42.5	5	383	162.7
16	Polyglycolide	0.021	5	351	37.1																		
17	Polyglycolide	0.018	5	212	40.8																		
18	Polyglycolide	0.015	5	95	4.1																		
19	Polyglycolide	0.015	5	145	4.9																		
20	67/33 gly/TMC	0.018	6	251	40.4	5	249*	48.6	5	217	62.3	4	175	24.8	5	127	13.4	5	101	31.8	5	63	26.4
21	25/75 gly/lac	0.021	5	323	17.4																		
22	25/75 gly/lac	0.018	5	311	29.1																		
23	25/75 gly/lac	0.015	5	117	25.9																		
24	PET	0.018	5	276	48.3																		
25	PET	0.015	5	187	17.5																		
26	PET	0.015	5	189	12.6																		
27	PBT	0.018	unable to form staple																				
28	HDPE	0.021	5	218	15.0																		
29	HDPE	0.018	5	164	13.0																		

1 in = 25.4 mm

<

TABLE 9 (continued)

Opening Strength (g)

			In Vitro Time (days)																				
Table 6a			0 Days			7 Days			14 Days			21 Days			28 Days			35 Days			42 Days		
Sample	Polymer	Diam. (in)	n	Mean	S.D.	n	Mean	S.D.	n	Mean	S.D.	n	Mean	S.D.	n	Mean	S.D.	n	Mean	S.D.	n	Mean	S.D.
30	HDPE	0.018	5	203	28.8																		
31	HDPE	0.018	5	157	25.6																		
32	HDPE	0.015	5	124	13.6																		
33	Polybutester	0.021	Unable to form staple																				
34	Polybutester	0.018	Unable to form staple																				
35	Polybutester	0.015	Unable to form staple																				
36	PP	0.021	Unable to form staple																				
37	PP	0.018	Unable to form staple																				
38	PP	0.015	Unable to form staple																				

1 in = 25,4 mm

Table 10

Creep Test Results					
		Mean Displacement (inches)		Percent (Displacement)	
Wt. in Air (grams)		72	50	72	50
Baseline (inches)		(0.079)	(0.074)	-	-
Time	(days)				
	0.042	0.001	0.001	1.29	1.38
	1	0.006	0.004	7.62	5.45
	3	0.011	0.009	13.97	11.79
	6	0.014	0.011	17.74	14.42
	8	0.014	0.011	17.74	14.42
	11	0.014	0.011	17.74	14.42
	13	0.014	0.011	17.74	14.42
	14	0.014	0.011	17.74	14.42
	17	0.014	0.011	17.74	14.42
1 inch = 25,4 mm					

Claims

1. A one piece surgical repair device consisting of a bioabsorbable polymeric wire (10) characterized in that the wire (10) is formed of an oriented, semicrystalline polymer, the polymer being a homopolymer of polylactic acid or polyglycolic acid, a block copolymer characterized by lactic acid ester linkages wherein said block copolymer can comprise linkages prepared from monomers selected from the group consisting of ε-caprolactone and 1,3-dioxan-2-one, or a multi-phase polymer derived from lactide and glycolide, wherein the one piece surgical repair device is capable of permanent flexural deformation at ambient temperature which is obtainable by extruding the polymer to form a polymeric extrudate, and subsequently quenching at 25°C and drawing the extrudate in at least one stage at a draw ratio of greater than 1X to less than 12X.

2. The device of claim 1 wherein the polymeric wire has a Young's modulus of greater than $4{\cdot}2{\cdot}10^4$ kg/cm^2 (600,000 psi).

3. The device of claim 2 which is a staple (10) consisting of a block copolymer comprising more than 50 mole percent of lactic acid ester linkages and the remaining linkages are prepared from ε-caprolactone.

4. The device of claim 1 characterized by a continuous phase having a glass transition temperature under in vivo conditions of more than 37°C.

5. The device of claim 4 which is a sterile surgical staple (10) useful in mammalian tissue.

6. The device of claim 4 which is a surgical staple (10) having a diameter of 0,13 to 1,3 mm (0.005 to 0.050 inches) and a Young's modulus of greater than $5{\cdot}6{\cdot}10^4$ kg/cm^2 (800,000 psi), and maintaining at least 50 percent of its initial strength after 21 days in-vivo.

7. The device of claim 6 wherein the polymeric wire comprises a bioabsorbable block copolymer having at least 80 mole percent of lactic acid ester linkages and the remaining linkages are prepared from ε-caprolactone.

8. A process for manufacturing the one piece surgical repair device of any one of claims 1 to 7 characterized by

   extruding a polymer to form a polymeric extrudate in the form of a wire;
   quenching the wire at 25°C;
   drawing said polymeric wire in at least one stage at a draw ratio of greater than 1X to less than 12X to form a polymeric wire;
   forming at least one curve in said polymeric wire by bending it over a fixture having at least one curved surface;

and
cutting at least one end of said polymeric wire to form the one piece surgical repair device.

Patentansprüche

1. Einstückige chirurgische Reparaturvorrichtung aus einem bioabsorbierbaren polymeren Draht (10), dadurch gekennzeichnet, dass der Draht (10) aus einem orientierten, semikristallinen Polymer gebildet ist, wobei das Polymer aus einem Homopolymer aus Polymilchsäure oder Polyglykolsäure, einem Blockcopolymer, das gekennzeichnet ist durch Milchsäureesterverknüpfungen, wobei das Blockcopolymer Verknüpfungen umfassen kann, die aus Monomeren, ausgewählt aus der Gruppe, bestehend aus ε-Caprolacton und 1,3-Dioxan-2-on, gebildet sind, oder einem Mehrphasenpolymer, das aus Lactid und Glycolid stammt, hergestellt ist, wobei die einstückige chirurgische Reparaturvorrichtung zur permanenten Biegeverformung bei Raumtemperatur geeignet ist sowie erhältlich ist durch Extrudieren des Polymers, um ein polymeres Extrudat zu bilden, und nachfolgendem Abschrecken bei 25°C und dem Ziehen des Strangpresslings (Extrudats) in wenigstens einer Stufe bei einem Ziehverhältnis von größer als 1X bis weniger als 12X.

2. Vorrichtung nach Anspruch 1, wobei der polymere Draht einen Elastizitätsmodul von mehr als $4{,}2 \cdot 10^4$ kg/cm^2 (600.000 psi) aufweist.

3. Vorrichtung nach Anspruch 2, die eine Klammer (10) ist, die aus einem Blockcopolymer besteht, das mehr als 50 Molprozent an Milchsäureesterverknüpfungen umfasst, und wobei die übrigen Verknüpfungen aus e-Caprolacton hergestellt sind.

4. Vorrichtung nach Anspruch 1, gekennzeichnet durch eine kontinuierliche Phase, die eine Glasübergangstemperatur von mehr als 37°C unter in vivo Bedingungen aufweist.

5. Vorrichtung nach Anspruch 4, die eine sterile chirurgische Klammer (10) ist, die für Gewebe von Säugern geeignet ist.

6. Vorrichtung nach Anspruch 4, die eine chirurgische Klammer (10) ist, die einen Durchmesser von 0,13 bis 1,3 mm (0,005 bis 0,050 Inch) und einen Elastizitätsmodul von mehr als $5{,}6 \cdot 10^4$ kg/cm^2 (800.000 psi) aufweist, und die in vivo nach 21 Tagen mindestens 50 Prozent der anfänglichen Festigkeit beibehält.

7. Vorrichtung nach Anspruch 6, wobei der polymere Draht ein biologisch aufnahmefähiges oder biologisch verträgliches Blockcopolymer umfasst, das mindestens 80 Molprozent an Milchsäureesterverknüpfungen aufweist, und und die übrigen Verknüpfungen aus ε-Caprolacton hergestellt sind.

8. Verfahren zur Herstellung der einstückigen chirurgischen Reparaturvorrichtung gemäß einem der Ansprüche 1 bis 7, gekennzeichnet durch Extrudieren eines Polymers, um ein polymeres Extrudat in Form eines Drahtes zu bilden; Abschrecken des Drahtes bei 25°C; Ziehen des polymeren Drahtes in mindestens einem Schritt bei einem Ziehverhältnis von mehr als 1X bis weniger als 12X um einen polymeren Draht zu bilden; Bilden mindestens einer Krümmung in dem polymeren Draht durch Biegen des Drahts über eine Fixiervorrichtung, die mindestens eine gekrümmte Oberfläche aufweist; und Abschneiden mindestens eines Endes des polymeren Drahtes, um die einstückige chirurgische Reparaturvorrichtung zu bilden.

Revendications

1. Dispositif de réparation chirurgical en une pièce, consistant en un fil de polymère biorésorbable (10), caractérisé en ce que le fil (10) est formé d'un polymère semicristallin orienté, le polymère étant un homopolymère d'acide polylactique ou d'acide polyglycolique, un copolymère séquencé caractérisé par des liaisons ester d'acide lactique, ledit copolymère séquencé pouvant comprendre des liaisons préparées à partir de monomères choisis parmi l'ε-caprolactone et la 1,3-dioxan-2-one, ou un polymère polyphasique dérivé de lactide et de glycolide, le dispositif de réparation chirurgical en une pièce pouvant être déformé par flexion de manière permanente à température ambiante, et il peut être obtenu en extrudant le polymère pour former un extrudat de polymère, et en refroidissant ensuite brusquement à 25 °C et en étirant l'extrudat en au moins une étape selon un taux d'étirage supérieur à 1 et inférieur à 12.

2. Dispositif selon la revendication 1, dans lequel le fil de polymère a un module d'Young supérieur à $4{,}2.10^4$ kg/cm^2. (600 000 psi).

3. Dispositif selon la revendication 2 consistant en une agrafe (10) constituée d'un copolymère séquencé comprenant plus de 50 moles % de liaisons ester d'acide lactique, et les liaisons restantes étant dérivées de l'ε-caprolactone.

4. Dispositif selon la revendication 1, caractérisé par une phase continue ayant une température de transition vitreuse dans des conditions in vivo, supérieure à 37 °C.

5. Dispositif selon la revendication 4, consistant en une agrafe chirurgicale stérile (10) utile dans un tissu de mammifère.

6. Dispositif selon la revendication 4, consistant en une agrafe chirurgicale (10) ayant un diamètre de 0,13 à 1,3 mm (de 0,005 à 0,050 pouce) et un module d'Young supérieur à $5{,}6.10^4$ kg/cm^2 (800 000 psi), et conservant au moins 50 % de sa résistance initiale après 21 jours in vivo.

7. Dispositif selon la revendication 6 dans lequel le fil de polymère comprend un copolymère séquencé biorésorbable comportant au moins 80 moles % de liaisons ester d'acide lactique, et les liaisons restantes étant dérivées de l'ε-caprolactone.

8. Procédé de fabrication du dispositif de réparation chirurgical à une pièce selon l'une quelconque des revendications 1 à 7, caractérisé en ce qu'il comprend les étapes consistant :

   à extruder un polymère pour former un extrudat de polymère sous forme d'un fil ;
   à refroidir brusquement le fil à 25 °C ;
   à étirer ledit fil de polymère en au moins une étape selon un taux d'étirage supérieur à 1 et inférieur à 12 pour former un fil de polymère ;
   à former au moins une courbe dans ledit polymère en le cintrant sur un dispositif de serrage comportant au moins une surface cintrée ; et
   à couper au moins une extrémité dudit fil de polymère pour former le dispositif de réparation chirurgical à une pièce.

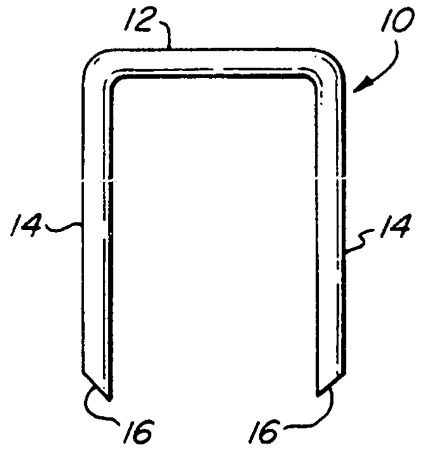

FIG. 1

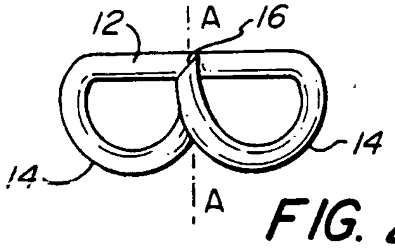

FIG. 2

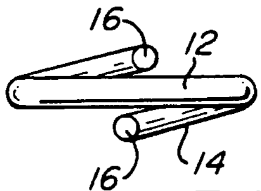

FIG. 3

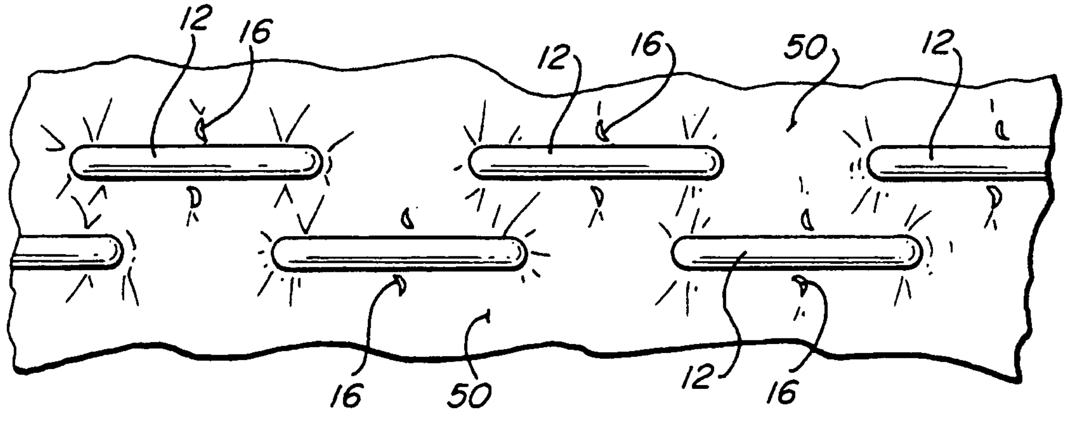

FIG. 4

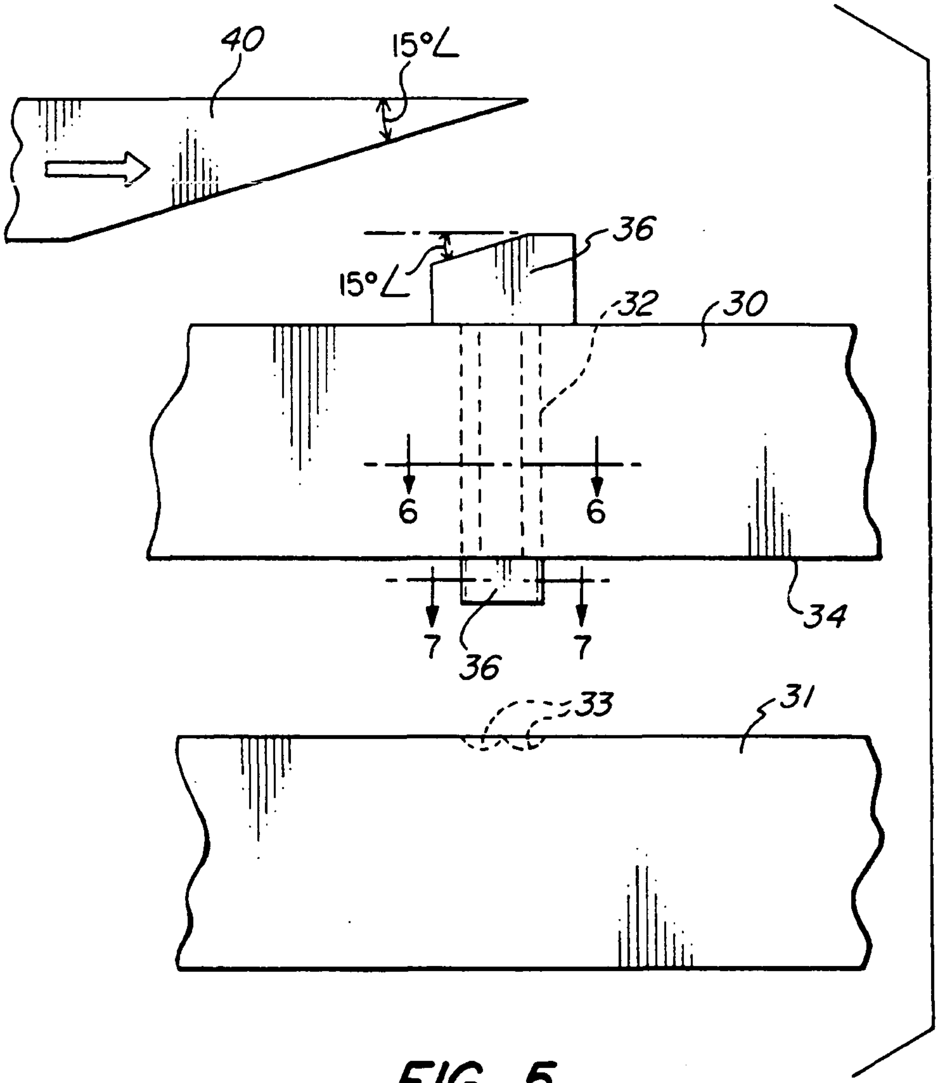

FIG. 5

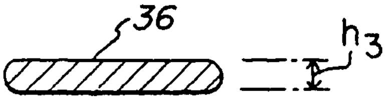

FIG. 7

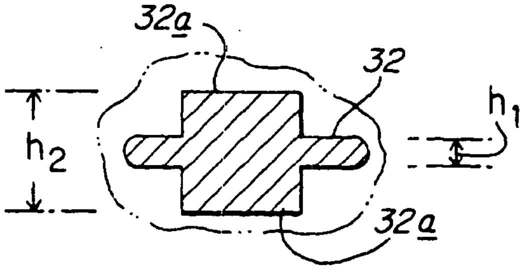

FIG. 6

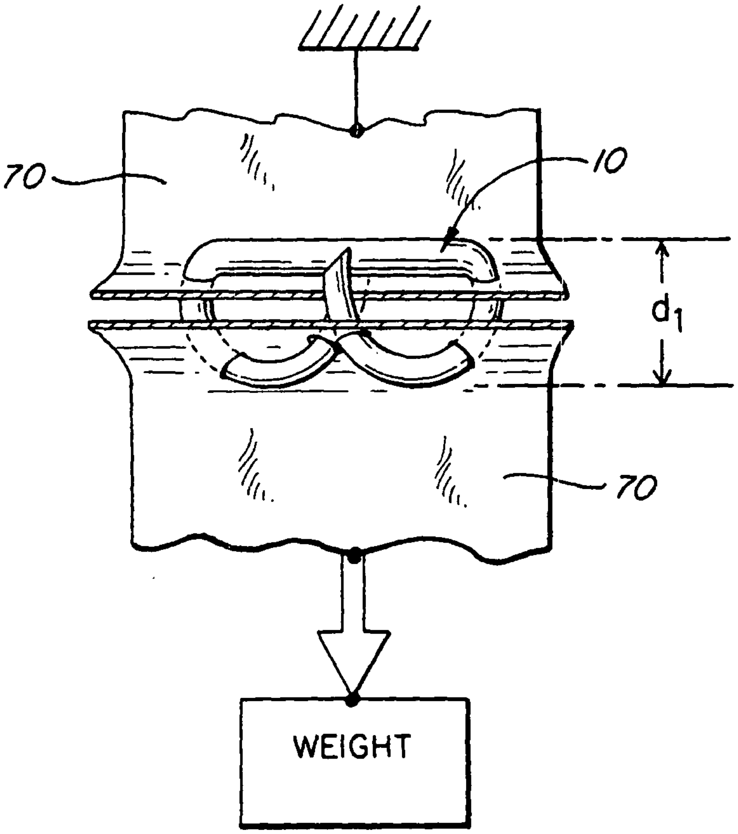

FIG. 8

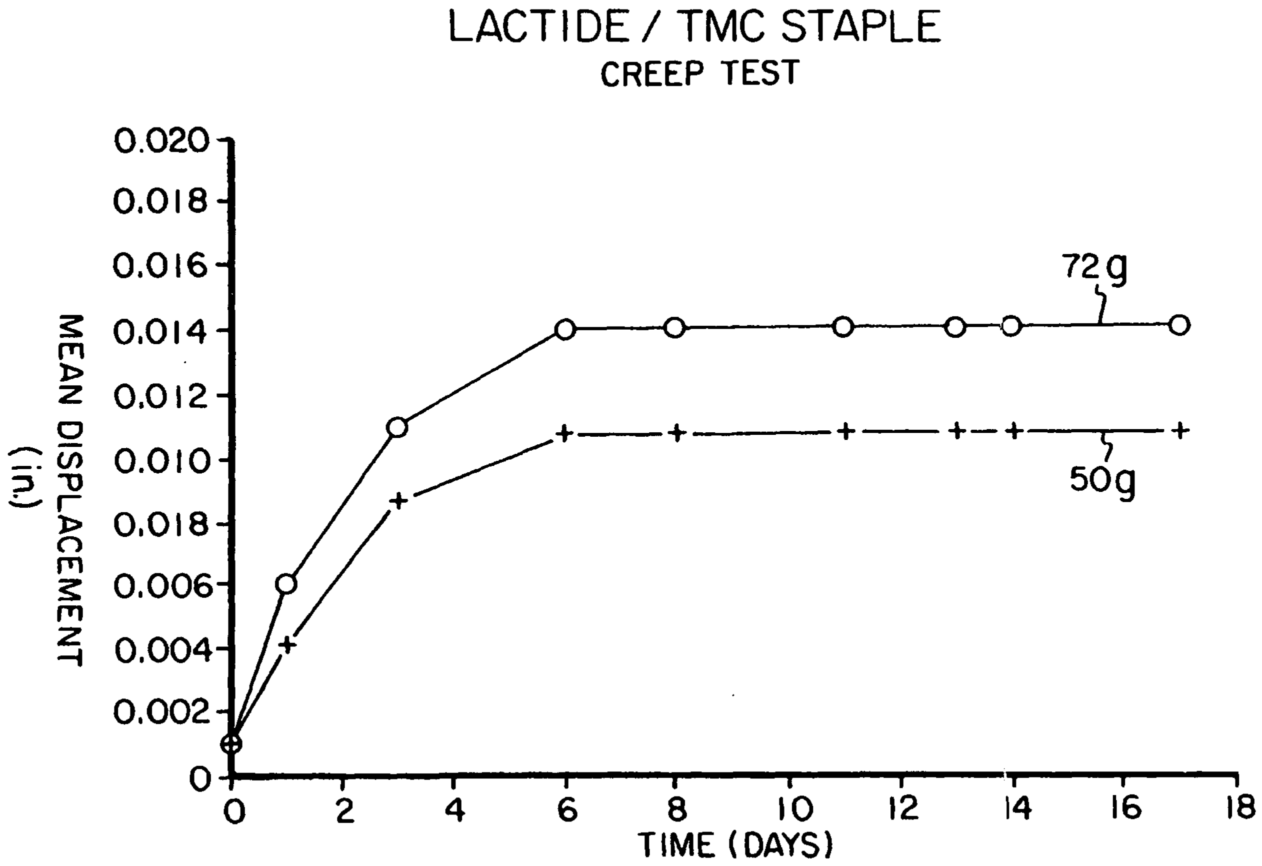
LACTIDE / TMC STAPLE
CREEP TEST
MEAN DISPLACEMENT
(in.)
0.020
0.018
0.016
0.014
0.012
0.010
0.018
0.006
0.004
0.002
0
0
2
4
6
8
10
12
14
16
18
TIME (DAYS)
72g
50g

FIG. 9